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INDUSTRY, EXPERTS TRY TO SELL FDA NANOTECH PANEL ON STATUS QUO

At a Tuesday (Oct. 10) meeting by the FDA advisory panel on nanotechnology, the cosmetics lobby announced an upcoming, voluntary data exchange program in a bid to counter consumer advocates' calls for FDA to increase scrutiny of products containing nano-sized particles. Most industry representatives and researchers testified that FDA's current regulatory framework is adequate to deal with nanotech, but that the agency needs additional resources to review the increasing number of drugs, devices, food additives and consumer care products submitted for approval.

Several speakers said the small size and great surface area of nanoparticles does not necessarily increase their toxicity, and that nanotech products should be evaluated on a case-by-case basis.

"Science does not yet mandate draconian measures," said **University of Michigan** Center for Risk Science and Communication Executive Director Martin Philbert. "Simply stated, at present the benefits of using nano-materials greatly outweigh the risks."

National and international standard-setting bodies have not yet agreed on an official definition of "nano," although the Bush administration generally refers to nanoparticles as being 100 nanometers or smaller.

One speaker, Abraxis BioScience Inc. Vice President For Research and Development Neil Desai, called the threshold "arbitrary" and suggested FDA align it -- at least for pharmaceuticals -- with the average pore size of filters used during filtration of sterile pharmaceuticals, 220 nanometers. Roughly 80 percent of research on nanoparticles is done on particles larger than 100 nanometers, he noted.

The vocal opposition against classifying nano-sized particles as new chemicals drowned out, by some accounts, advocacy groups such as Consumers Union and Environmental Defense, which are pushing for stricter pre- and post-marketing safety tests especially for consumer care products such as sunscreens, many of which have already been approved by FDA.

Currently, FDA does not have the authority to require safety trials before approving consumer care products, but may take them off the market if health risks become known later.

The Cosmetic, Toiletry, and Fragrance Association (CTFA) argues that consumer care products are generally safe because manufacturers conduct rigorous tests prior to approval.

"[T]he scientific methods currently used to ensure the safety of existing and new substances ... are equally appropriate for evaluating the safety of ingredients developed in the nano-scale range," the trade group argues in a white paper released Tuesday.

CTFA says evidence shows that nanoparticles in sunscreens are unlikely to enter the body and, as some news reports suggested, "cling" to organs and potentially damage the brain. These products, CTFA notes, help prevent skin cancer and "consumers have not experienced any toxicities or deleterious effects from these products."

The group is setting up a "consumer commitment code" that CTFA officials say will increase FDA access to often unpublished safety studies conducted by manufacturers. Starting January 2007, some 600 CTFA members can pledge to submit information on their products' ingredients to FDA's voluntary cosmetic registration program and provide FDA with additional safety data upon request. Serious adverse events would have to be reported to FDA immediately, according to the code.

Asked whether companies may still refuse to provide certain information, a CTFA official told FDA Week that it will be entirely up to the companies to adhere to the code once they sign it.

CTFA officials also noted that 13,000 ingredients have so far been checked by the CTFA-funded cosmetic ingredient review process, established in 1976.

Environmental Working Group Vice President for Research Jane Houlihan and University of Maryland School of Public Health Professor Michael Taylor said FDA should require consumer care products to carry warning labels where the safety of nanoparticles hasn't been established. If a product, such as a sunscreen, was found to enter and alter the body, FDA would classify it as a drug and require appropriate tests.

"For drugs, FDA has a regulatory framework that's satisfactory," Taylor said, echoing other speakers such as Crowell & Moring attorney Matthew Jaffe, who testified on behalf of the U.S. Council for International Business.

The public meeting was called by FDA's internal nanotechnology task force, appointed in August 2006. Additional comments are due Nov. 10. The group of experts is planning to release a report with policy recommendations within nine months. No further events are planned at this point.